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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,654	12/12/2003	Mark T. Muldoon	19596-0562 (45738-294842)	9327

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,654	MULDOON ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-21* is/are pending in the application.

4a) Of the above claim(s) *14 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-13 and 17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/30/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 02/14/05 is acknowledged and has been entered.

Claim Objections

1. Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 12 recites "the method detects rendered animal byproduct in the sample in amount of about 0.1% by weight or more". This limitation fails to further limit the recitation of claim 1 reciting "0.005% to about 0.5%".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-8, 10-13, 15, and 17-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 21, lines 6-22 in the specification. The applicant discloses the assays detect rendered animal product

in concentrations as low as about 0.50% and above by weight. In some embodiments, the assays detect rendered animal product in concentrations as low as about 0.10% and above by weight. In some embodiments, the assays detect rendered animal product in concentrations as low as about 0.05% and above by weight. In some embodiments, the assays detect rendered animal product in concentrations as low as about 0.01% and above by weight. In some embodiments the assays detect rendered animal product in concentrations as low as about 0.005% and above by weight. The applicant does not disclose the amount of rendered animal byproduct detected by the method is about 0.005% to about 0.5 % (as recited in claim 1). There is no description in the specification disclosing the range with a low limit of 0.005% and an upper cutoff of 0.5%. Further there is no description in the specification disclosing the range 0.005% to about 0.01% as recited in claim 18.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-8, 10-13, 15, and 17-21 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because the preamble of the claim recites detecting rendered animal byproduct in a sample and it is unclear how one can detect rendered animal byproduct in the circumstance of the non-existence of the complex. Claim 1, line 12 the recitation "component thereof" is vague and indefinite. It is unclear

what applicant is referring to. There is no definition provided for the term in the specification.

Claim 1, line 14 the recitation "by weight" is vague and indefinite. It is unclear what applicant is referring to. By weight of what? Does applicant intend the weight of the feed sample to the byproduct or total volume to initial volume or does applicant intend the weight of the byproduct in the solutions containing the sample, or does applicant intend the sensitivity of the assay? Please clarify. See also deficiencies found in claims 18-21.

Claim 15 the recitation "materials useful in performing" is vague and indefinite. It is unclear what materials applicant is referring to. Is applicant referring to the detactable ligand, a sample or does applicant intend some other materials? Please clarify which materials are included in the kit.

Claim 17 the recitation "the detectable label" there is insufficient antecedent basis for this limitation. The first recitation of a detectable label appears in claim 2.

Claims 18-21 are vague and indefinite because it is unclear what applicant intends. Does applicant intend that the sample to be detected (the animal feed which comprises the rendered animal product) is included in a kit. Does applicant intend for the rendered animal byproduct recited is to be a control included in the kit. Please clarify.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 8, 12, and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Chen et al., (Monoclonal antibodies against troponin I for the detection of rendered muscle tissues in animal feed stuffs, meat Science (2002), 62 (4), 405-412.

Chen et al disclose a method for detecting rendered muscle in animal feedstuff. Chen et al disclose the use of an ELISA immunoassay in which sample suspected of comprising an analyte is combined with antibody (ligand). Chen et al disclose that the ligand can be detected by the addition of a second antibody that is labeled with an enzyme (p. 407). Chen et al disclose wash steps to remove unbound complexes. Chen et al disclose measuring a signal generated and determining the presence of the analyte. Chen et al disclose the addition of antibodies in ELISA assay that have measurably lower binding affinity for one or more different species (taxonomic groups) (p. 409-411). Chen et al disclose that the ELISA can be in the form of an indirect ELISA or a sandwich ELISA (p. 411).

With respect to the recitation the amount of rendered animal byproduct detected by the method is about 0.005% to about 0.5% as recited in the instant claims. Chen et al discloses that the detection limit of the mammalian and ruminant assays were between 0.3 and 2% and that if sandwich ELISA assays are performed the assay

sensitivity could be enhanced such as 0.1% or less(p. 411, 1st column), which fall within the recited range and further, it is unclear what applicant intends by the recitation "by weight". Therefore, Chen et al reads on the instantly recited claims.

8. Claims 1, 8, 12, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Hsieh et al. (US 2003/0022248).

Hsieh et al disclose a method for detecting rendered muscle in animal feedstuff. Chen et al disclose the use of an ELISA immunoassay in which sample suspected of comprising an analyte is combined with antibody (ligand). Hsieh et al disclose that the ligand can be detected by the addition of a second antibody that is labeled with an enzyme. Hsieh et al disclose wash steps to remove unbound complexes. Hsieh et al disclose measuring a signal generated and determining the presence of the analyte. Hsieh et al disclose the addition of antibodies in ELISA assay that have measurably lower binding affinity for one or more different species (taxonomic groups). Hsieh et al disclose that the ELISA can be in the form of an indirect ELISA , a sandwich ELISA or a competitive assay (paragraph 0030 & 0085). Hsieh et al disclose packing the components into a kit (paragraph 0030). Hsieh et al also disclose that the analyte of interest can be skeletal troponin.

With respect to the recitation the amount of rendered animal byproduct detected by the method is about 0.005% to about 0.5% as recited in the instant claims. Hsieh et al discloses that the detection limit of the mammalian and ruminant assays were between 0.3 and 2% and that if sandwich ELISA assays are performed the assay sensitivity could be enhanced such as 0.1% or less(paragraph 0085), which fall within

the recited range and further, it is unclear what applicant intends by the recitation "by weight". Therefore, Hsieh et al reads on the instantly recited claims.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 2 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voller (The Enzyme Linked Immunosorbent Assay, Diagnostic Horizons, Vol. 2, No. 1, 1978).

See above for teachings of Hsieh et al.

Hsieh et al differ from the instant invention in failing to specifically teach the ligand has a detectable label and a second ligand that is bound to at least one location on a solid phase.

Voller disclose ELISA assays for determining an analyte of interest. Voller disclose a double antibody sandwich ELISA for measuring an antigen of interest. Voller disclose an enzyme labeled antibody (ligand) for binding to the antigen and a second antibody (ligand) bound to a solid phase (p. 2). Voller discloses that the ELISA is a versatile tool and can be used for the quantitation of virtually any antibody and high molecular weight antigen.

It would have been obvious to one of ordinary skill in the art to incorporate a labeled ligand and immobilized ligand as taught by Voller in the method of Hsieh et al because Hsieh et al specifically teaches that the antibodies of Hsieh et al can be used double sandwich ELISA assays and further because Voller teaches that the ELISA is a versatile tool and can be used for the quantitation of virtually any antibody and high molecular weight antigen.

13. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hsieh et al in view of Schuurs et al (US 3,654,090) and further in view of Deger et al (US 5,437,981).

See above for teachings of Hsieh et al.

Hsieh et al differs from the instant invention in failing to teach an analyte analog that is bound to at least one location on a solid phase, wherein the ligand has a binding affinity for the analyte analog.

Schuurs et al disclose a method for the determination of a component of the antigen-antibody reaction. Schuurs et al disclose that the test system can be composed of antigen, labeled antibody (ligand) and immobilized antigen and that the labeled antibody has binding affinity for the immobilized antigen (col 2, lines 66-69). Schuurs et al discloses that a good separation between the bound and free labeled component is essential (lines 43-44). Schuurs et al discloses that this assay format provides a method for assaying substances in very small quantities for a very high sensitivity (col 3, lines 15-18).

It would have been obvious to one or ordinary skill in the art to incorporate testing methods as taught by Schuurs et al into the method of Hsieh et al because Hsieh et all specifically teaches competitive assays can be used to determine the antigen of interest and further because Schuurs et al teaches that this assay format provides a method for assaying substances in very small quantities for a very high sensitivity.

Hsieh et al and Schuurs et al fail to teach the use of an analyte analog.

Deger et al. disclose competitive immunoassays used to determine an analyte of interest (col. 1). Deger et al disclose an immobilized analog (col 1, lines57-60). Deger

et al disclose combining the sample containing the ligand (analyte) and antibody (ligand) with the immobilized analog.

It would have been obvious to one or ordinary skill in the art to substitute an immobilized analog as taught by Deger et al for the immobilized antigen of the modified method of Hsieh et al because Deger teaches it is known in the art to use analogs as reagents in competitive immunoassays. Further, the use of analyte analog in immunoassays is very well known in the art and therefore would be considered an obvious substitution for an immobilized antigen.

14. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hsieh et al in view of Jacobs et al (US 5,571,682) Guan et al (US 6,617,116)

See above for teachings of Hsieh et al.

Hsieh et al differs from the instant invention in failing to teach combining the sample and ligand with a labeled analyte analog and the ligand immobilized.

Jacobs et al disclose different types of immunoassays and teach that in competitive assay, a labeled analog of the target analyte to be determined is placed in competition with the analyte for a fixed amount of an appropriate, immobilized antibody (ligand) which can react with either the target analyte or a target analyte analog (col 1, lines 20-32). Jacobs et al disclose that this method provides for a means for determining how much target analyte is in the sample.

Guan et al disclose a competitive immunoassay for determining an analyte of interest. Guan et al disclose that analyte in sample competes with labeled analogue to the analyte, for a binding partner immobilized on a solid support (col 1, lines 37-40).

Guan et al disclose that a competitive immunoassay provides a quantitative measure of analtye concentration (col 1, lines 46-48).

It would have been obvious to one of ordinary skill in the art to incorporate competitive immunoassays as taught by Jacobs et al into the method of Hsieh et al because Hsieh et al specifically teaches that competitive assays can be used and further because Jacobs et al shows that this type of immunoassay provides for a means for determining how much target analyte is in the sample. Further, the use of competitive immunoassays using labeled analyte analogs is very well known in the art.

It also would have been obvious to one of ordinary skill in the art to incorporate competitive immunoassays as taught by Guan et al into the method of Hsieh et al because Hsieh et al specifically teaches that competitive immunoassays can be used and further because Guan et al shows that this type of immunoassay provides a quantitative measure of analyte concentration. Further, the use of competitive immunoassays using labeled analyte analogs is very well known in the art.

15. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsieh et al in view of Ansfield US 5,910,446).

See above for teachings of Hsieh et al.

Hsieh et al differ from the instant invention in failing to teach the analyte is a component of meat and bone meal.

Ansfield discloses immunoassays to detect ruminant proteins in rendered animal materials . Ansfield discloses ELISA systems to determine an analyte of interest (col 3, lines 19-26). Ansfield discloses combining the sample and reagents and

detecting a signal of the labeled antibodies bound to the protein. Ansfield discloses that the sample can be meat and bone meal.

It would have been obvious to one of ordinary skill in the art to detect meat and bone meal proteins such as taught by Ansfield the method of Hsieh et al because Hsieh et al teaches the detection of rendered animal tissues in animal feed and teaches that the detection of undeclared exogenous meat is important to comply with the animal feed regulation and Ansfield teaches detecting proteins in meat and bone meal. Further, Hsieh et al disclose that ELISA's can be used with meat and bone meals (para. 0085). Therefore, one of ordinary skill in the art would have a reasonable expectation of success detecting proteins found in meat and bone meal using the method of Hsieh et al.

16. Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsieh et al. (US 2003/0022248) in view of Thorn et al (US 2003/0083255).

See above for teachings of Hsieh et al.

Hsieh et al differ from the instant invention in failing to specifically teach the analyte is a component of cartilage.

Thorn et al disclose that Troponin I is a component of cartilage (a connective tissue) (paragraph 0034 & 0154).

It would have been obvious to one of ordinary skill in the art that the skeletal troponin as taught by Hsieh et al is a component of cartilage because Thorn et al teaches that Troponin I is a component of cartilage.

17. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hsieh et al in view of Radziejewski et al (US 6,022,694).

See above for teachings of Hsieh et al.

Hsieh et al differ from the instant invention in failing to teach the analyte is Type II collagen.

Radziejewski et al disclose assays for detecting Type II collagens in a sample (col 21). Radziejewski et al discloses that ligand binding assays are useful in determining the presence and concentration of ligands in food products (col 2). Radziejewski et al disclose that using such assays to determine the presence and concentration of specific analytes has significantly improved medical diagnosis.

It would have been obvious to one or ordinary skill in the art to incorporate assays to detect Type II collagen as taught by Radziejewski et al into the method of Hsieh et al because Hsieh et al teach that the accurate labeling of meat products is mandated and monitored by the United States Department of Agriculture as well as by state and local governments (paragraph 0004) and controls to prevent the spread of BSE have prohibited the use of certain animal proteins in feed , requiring accurate analytical methods for detecting prohibited material in feed stuffs (para. 0012). Therefore, one of ordinary skill in the art would test a sample for components in order to accurately label the product. Further, Radziejewski et al discloses that ligand binding assays are useful in determining the presence and concentration of ligands in food products (col 2). Radziejewski et al disclose that using such assays to determine the presence and concentration of specific analytes has significantly improved medical

diagnosis. Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating binding assays for Type II collagen in the method of Hseih et al.

18. Claims 15 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsieh et al. (US 2003/0022248) in view of Foster et al (US 4,444,879).

See above for teachings of Hsieh et al.

Hsieh et al differ from the instant invention in failing to teach the kit contains instructions.

Foster et al disclose packing components and instructions for performing a method into a kit (col 15, lines 11-34).

It would have been obvious to one of ordinary skill in the art to incorporate instructions as taught by Foster et al into the kit of Hsieh et al. because Foster et al teaches packing components and instructions for performing a method into a kit. Further, the kit would provide guidance and make it more facile and convenient for the test operator.

With respect to claims 18-21 Hsieh et al discloses that the detection limit of the mammalian and ruminant assays were between 0.3 and 2% and that if sandwich ELISA assays are performed the assay sensitivity could be enhanced such as 0.1% or less (paragraph 0085), which fall within the recited ranges and further, it is unclear what applicant intends in claims 18-21 (see 112 rejection above). Therefore, Hsieh et al and Foster reads on the instantly recited claims.

Response to Arguments

19. Applicant's arguments filed 02/14/05 have been fully considered but they are not persuasive.

Applicant argues that the weight percentage meat meal ranges utilized by Chen et al., are 1%, 5%, 25%, and 50% and that these ranges are outside the limitation recited in amended Claim 1, wherein the amount of rendered animal byproduct is about 0.005% to about 0.5% by weight. This is not found persuasive because as stated above Chen et al discloses that the detection limit of the mammalian and ruminant assays were between 0.3 and 2% and that if sandwich ELISA assays are performed the assay sensitivity could be enhanced such as 0.1% or less(p. 411, 1st column), which fall within the recited range and further, it is unclear what applicant intends by the recitation "by weight". Therefore, Chen et al reads on the instantly recited claims.

With respect to the 103 arguments directed to the claims. The arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art unit 1641
March 22, 2005

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03/31/05